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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,739	10/20/2000	Thomas Valentine McCarthy	1377-156P	3757
2292	7590	06/12/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 06/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No. 09/673,739	Applicant(s) MCCARTHY ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 5/23/06 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-21 and 23.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: please see the attached.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

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The applicant's response filed 5/23/06 to the Office action have been entered. Claims 1-21 and 23 are pending.

1. The rejection of claims 1-21 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

2. Claims 1-21 and 23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dianov et al. (Molecular and Cellular Biology, 1992, Vol. 12(4), pg. 1605-1612) in view of McCarthy et al. (5,952,176, issued September 14, 1999).

Dianov et al. disclose that the extent and location of DNA repair synthesis in a double stranded oligonucleotide containing a single dUMP residue have been determined in which the repair pathway of a dUMP residue in DNA involves uracil- DNA glycosylase and incision of the phosphodiester bond 5' to AP site by an AP endonuclease and baseless sugar-phosphate residue could be excised by a dRpase or a 5'-3'exonuclease to leave a hydroxyl group at the 3' terminus (See pg. 1606, fig, 1) and then the polymerase step occur either after or before the excision step. The excision step is catalyzed usually by a DNA deoxyribophosphodiesterase (See pg. 1605, the Abstract).

Dianov et al. do not disclose that the modified base is introduced by enzyme extension of the molecule on a template nucleic acid.

McCarthy et al. disclose a novel process for the detection of known mutation and polymorphisms in DNA. The process involves amplification, which incorporates modified precursor nucleotides into the amplified products. The amplified products are one or more glycosylase substrate (See column 5, lines 7-9 and column 5, lines 49-60).

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One of ordinary skill in the art would have been motivated by applying enzymatic extension of the DNA molecule on a template nucleic acid to introduce a modified base as taught by McCarthy et al. because the method of McCarthy can be used to detect multiple known mutations by using a single enzyme and a single process (See column 5, lines 18-20). It would have been prima facie obvious to apply enzymatic extension of the DNA molecule on a template nucleic acid to introduce a modified base for characterizing nucleic acid sequence.

The response argues that Dianov et al. fails to teach the specificity of the primers generated with the 3'-OH end which is determined by the target nucleic acid. However, the limitation recited in <sup>the</sup> "wherein" clause that specificity of the fragment is determined by the sequence of the target nucleic acid has no patentable weight since the recitation is an effect. Moreover it is also obvious regarding the specificity of the primer which is stated in the argument for the rejection of claims 1-21 and 23 under 35 U.S.C. 112, second paragraph.

The response also argues that the examiner asserts that it would be obvious to use the enzymatic cleavage mechanism of Dianov et al. to generate a 3'-OH extendable fragment in the method of McCarthy et al. However, the reference of McCarthy et al. provided herein is to teach that in the method of McCarthy et al. there is a process involving amplification, which incorporates modified precursor nucleotides into the amplified products. The amplified products are one or more glycosylase substrate (See column 5, lines 7-9 and column 5, lines 49-60). Since the method of McCarthy et al. uses a single enzyme and a single process (See column 5, lines 18-20), it would have been prima facie obvious to apply enzymatic extension of the DNA molecule on a template nucleic acid to introduce a modified base as taught by McCarthy et al. for characterizing nucleic acid sequence. Based upon the analysis above, the rejection is maintained.


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### Summary

3. No claims are allowable.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung   
May 30, 2006

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER  
6/5/06